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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,303	01/26/2007	Hiromi Matsuzaki	P30093	5121

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EXAMINER

WOLF, MEGAN YARNALL

ART UNIT	PAPER NUMBER
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3738

NOTIFICATION DATE	DELIVERY MODE
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02/17/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/596,303	Applicant(s) MATSUZAKI ET AL.	
	Examiner Megan Wolf	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 14 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 14 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 8/10/10 have been considered but are moot in view of the new ground(s) of rejection.

Terminal Disclaimer

2. The terminal disclaimer filed on 8/10/10 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 7,238,209 has been reviewed and is NOT accepted. The terminal disclaimer is disapproved because the attorney that signed the terminal disclaimer does not match the attorney's name on the terminal disclaimer. Also, the language "35 USC 154 to 156 and 173" is unclear because 155 and 156 do not define the term of the patent. It should read 35 USC 154 and 173.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 14, and 19-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 7,238,209 in view of Kim et al. 5,645,596 (hereafter referred to as Kim) and in further view of Tofighi et al. 2003/0052829 (hereafter referred to as Tofighi). The claims of the application are not patentably distinct from the claims of the patent because they would have been obvious in view of the patent claims and in further view of Kim and Tofighi. Claims 1-15 of the patent only differ from the present claims because the present claims define a porosity of equal to or less than 75% and a collapsing strength of more than 15MPa.

Kim teaches a vertebral prosthesis, in the same field of endeavor, wherein calcium phosphate is used as an implant material for the purpose of its spontaneous adhesion to the associated vertebrae, and wherein the porosity of the calcium phosphate is preferably between 30 and 45% for the purpose of simultaneously providing mechanical strength and promoting tissue ingrowth (col.4, ll.32-46).

Tofighi teaches a calcium phosphate compound for use in an implant, in the same field of endeavor, wherein the final porous calcium phosphate compound has a compression strength of greater than 20MPa for the purpose of being useful as a weight bearing implant material (par.56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to specify that the porosity of the pellets be less than 75% and the collapsing strength of the pellets be more than 15 MPa in view of Kim and Tofighi in order to provide a material that is capable of providing strength while promoting tissue ingrowth.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8, 14, and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, lines 14 and 16-17, recites "each pellet", however, only a single pellet has been defined by the claim. The scope of the claim is unclear because it is not apparent whether there is a single pellet or a plurality of pellets. Please clarify.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-8, 14, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. 6,387,130 (hereafter referred to as Stone) in view of Shimp 2004/0052829 (hereafter referred to as Shimp) in further view of Kim et al. 5,645,596 (hereafter referred to as Kim) and in further in view of Tofighi et al. 2003/0120351 (hereafter referred to as Tofighi).

Re claim 1, Stone discloses the invention substantially as claimed including a bone replacement material to be used by being packed into a bone defective part, wherein the bone replacement material is a rigid biocompatible material and is formed into a pellet 20 wherein the pellet has a roughly polyhedral shape and is defined by a plurality of surfaces including a pair of opposite, non-parallel, and non-adjointed surfaces either opposite surfaces 22 or opposite surfaces 23 and 25, one of the opposite, non-parallel surfaces being inclined at a predetermined angle in the range of 20 to 40° with respect to the other of the opposite, non-parallel surfaces (figs 4A-5). The bone replacement material is also capable of being used in the manner claimed wherein each pellet is inserted into the hollow passage of the cylindrical member such that the inclined surface of the pellet faces the inclined surface of an adjacent pellet and the pellets are pushed out in various directions. Stone discloses pellets that have a longest

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edge, a shortest edge, and a volume (fig.5), but does not disclose the specific size of these dimensions wherein the longest edge is in the range of 5-10 mm, the shortest edge is in the range of 2-5 mm and the volume is in the range of 13 to 239 mm³ or that the material consists essentially of calcium phosphate.

Shimp teaches bone replacement pellets, in the same field of endeavor, wherein the pellets are formed of porous calcium phosphate for the purpose of resisting deformation or fracture under the physiologic loads normally experienced at the repair site (pars.28-30), and wherein the pellets can vary in size but are preferably up to about 4mm (yielding a volume of about 64mm³), for the purpose of providing an injectable load bearing support at the repair site (par.10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use calcium phosphate for the implant material in order to provide an implant material that resists deformation or fracture under the physiologic loads normally experienced at the repair site. It would have been further obvious to specify the claimed size ranges for the pellets of Stone as this size is best suited for injecting bone replacement material into a bone defect in the spine as taught by Shimp and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A). While Stone in view of Shimp discloses porous calcium phosphate pellets, Stone in view of Shimp does not specifically disclose that the porosity is equal to or less than 75% and that the collapsing strength is equal to more than 15Mpa.

Kim teaches a vertebral prosthesis, in the same field of endeavor, wherein calcium phosphate is used as an implant material for the purpose of its spontaneous adhesion to the associated vertebrae, and wherein the porosity of the calcium phosphate is preferably between 30 and 45% for the purpose of simultaneously providing mechanical strength and promoting tissue ingrowth (col.4, ll.32-46).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use calcium phosphate with a porosity of less than 75% as taught by Kim for the vertebral implants of Stone in view of Shimp in order to allow for tissue ingrowth for anchoring the implant while maintaining mechanical strength to resist compression forces. As Kim discloses the claimed porosity as well as the Ca/P ratio claimed in claim 19, one would assume that the collapsing strength of the calcium phosphate compound of Kim is equal to or more than 15 MPa. Still, Stone in view of Shimp in further view of Kim does not specifically state that the collapsing strength of the calcium phosphate based compound is 15MPa or more.

Tofighi teaches a calcium phosphate compound for use in an implant, in the same field of endeavor, wherein the final porous calcium phosphate compound has a compression strength of greater than 20MPa for the purpose of being useful as a weight bearing implant material (par.56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to specify that the calcium phosphate compound of Stone in view of Shimp in further view of Kim have a collapsing strength greater than 15Mpa in order to provide a

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material that is strong enough for use as an implant that is required to bear weight as taught by Tofighi.

Re claims 2-8 and 14, see Stone fig.4A. The claims define shapes that have a part cut off. This "cut off" part could result in the shape disclosed by Stone. Further, the claims define the shapes as "roughly" pentahedral, circumferential, etc. and the term "roughly" is very vague and broad. Therefore, the shape of the pellets of Stone may be interpreted as roughly pentahedral, circumferential etc.

Re claim 19, see Kim col.4, ll.25-30.

Re claim 20, see Stone fig. 3. Note that while Stone does not disclose that the implants are inserted into the hollow passage of a cylindrical member such that the inclined surface of a pellet faces the inclined surface of an adjacent pellet, because of their shape shown in fig.3, the pellets of Stone are capable of such use.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738